(18)

No. 04-607

FILED

DEC 23 2005

OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, dba LabCorp,

Petitioner,

v.

METABOLITE LABORATORIES, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICUS CURIAE BRIEF OF THE ASSOCIATION OF THE BAR OF THE CITY OF NEW YORK IN SUPPORT OF NEITHER PARTY

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INTEREST OF *AMICUS CURIAE*

Amicus Curiae the Association of the Bar of the City of New York is a private, non-profit organization of more than 22,000 attorneys, judges and law professors who are professionally involved in a broad range of law-related activities. Founded in 1870, the Association is one of the oldest bar associations in the United States. The Association seeks to promote legal reform and to improve the administration of justice at the local, state, federal and international levels through its more than 180 standing and special committees. The Committee on Patents ("the Committee") is a long-established standing committee of the Association, and its membership reflects a wide range of corporate, private practice and academic experience in patent law.[1]

DISCUSSION

This Court granted *certiorari* on Question No. 3 in the Petitioner's brief, which reads as follows:

> Whether a method patent setting forth an indefinite, undescribed and non-enabling step directing a party simply to "correlate" test results can validly claim a monopoly over a basic scientific relationship used in medical treatment

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1. The parties have consented to the filing of this brief *amicus curiae* and letters of consent have been filed in accordance with Rule 37.3. Pursuant to Rule 37.6, *amicus* represents that this brief was not authored in part or in whole by counsel for any party, and that no person or entity other than *amici* has made a monetary contribution to the preparation or submission of this brief.

> such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result.

(Petr.'s Br. 1.)

The Court invited the Solicitor General to file a brief expressing the views of the United States as to whether the patent claim at issue covers patentable subject matter under *Diamond v. Diehr*, 450 U.S. 175 (1981):

> Respondent's patent claims a method for detecting a form of vitamin B deficiency, which focuses upon a correlation in the human body between elevated levels of certain amino acids and deficient levels of vitamin B. The method consists of the following: First, measure the level of the relevant amino acids using any device, whether the device is, or is not, patented; second, notice whether the amino acid level is elevated and, if so, conclude that a vitamin B deficiency exists. Is the patent invalid because one cannot patent "laws of nature, natural phenomena, and abstract ideas"? *Diamond v. Diehr*, 450 U.S. 175, 185 (1981).

The patent in suit, U.S. Patent No. 4,940,658 ("the '658 patent") is directed to methods for detecting deficiencies of cobalamin (vitamin B12) and folate (folic acid). The inventors discovered a relationship between elevated levels of total homocysteine and a deficiency in either cobalamin or folate. *See Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1358 (Fed. Cir. 2004). The inventors also developed a test to identify which particular

vitamin is deficient using methylmalonic acid (the panel test) and this test is the subject of other claims of the patent not at issue here. *Id.*

Claim 13 of the '658 patent reads as follows:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> > Assaying a body fluid for an elevated level of total homocysteine;
> >
> > and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

The jury found claim 13 to be valid and infringed. At trial, the petitioner argued that the claim was invalid because it was anticipated by prior art under Section 102; was obvious in light of the prior art under Section 103; did not "distinctly claim" the invention under Section 112, second paragraph; and did not satisfy the written description requirement of section 112, first paragraph. 370 F.3d at 1359, 1366-67.

The patent holders argued at trial that doctors were direct infringers because they performed one of the steps recited in the claim, namely the "correlating step," and that LabCorp induced doctors to infringe by performing a test for total homocysteine and publishing information to the effect that an elevated level of total homocysteine correlates with cobalamin or folate deficiency. *Id.* at 1365. The record suggests that any competent doctor will necessarily perform the second "correlating step" when he receives the results of

any total homocysteine assay because it would be malpractice for a doctor to receive a total homocysteine assay without determining cobalamin/folate deficiency. *Id.* at 1364.

SUMMARY OF ARGUMENT

The standards for determining whether a patent claim covers patentable subject matter as enunciated in *Diamond v. Diehr* should be reaffirmed by the Court.[2] Reiteration of the Court's holding in *Diehr* is timely because recent statements by the United States Court of Appeals for the Federal Circuit concerning the analysis of patent claims that may implicate laws of nature have deviated from *Diehr*. In particular, the scope of the patent claim is an essential part of the analysis under *Diehr*. The examination of patentable subject matter under Section 101 should not be confused or conflated with an analysis of the other requirements for patentability under the Patent Act. The analysis under Section 101 should be treated as a separate threshold issue, as required by *Diehr*. The circumstances in which a Section 101 analysis is needed should not be restricted because it is impossible to predict the advances in technology that may make a Section 101 analysis necessary.

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2. While some amicus briefs in this case may raise the issue of the recent abandonment by the United States Patents and Trademark Office of its "technological arts" test for examining business method patents under Section 101, the Committee does not believe that the issue is raised in this case, nor that this case is a good vehicle to examine that issue.

ARGUMENT

I. THE STANDARDS FOR EVALUATNG PATENTABLE SUBJECT MATTER ENUNCIATED IN *DIEHR* ARE CLEAR AND SHOULD BE REAFFIRMED.

In enacting the Patent Act, Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952), H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952), *Diamond v. Diehr*, 450 U.S. at 182. Under Section 101 of the Patent Act a new and useful process, machine, manufacture or composition of matter qualifies as patentable subject matter. 35 U.S.C. § 101 (2000).

Although Section 101 defines broad categories of patentable subject matter, it does not embrace every new discovery. It is well established that laws of nature, natural phenomena and abstract ideas remain in the public domain and cannot be the subject of a patent, even to one who is the first to identify them. *Diehr*, 450 U.S. at 185; *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Parker v. Flook*, 437 U.S. 584, 589 (1978), *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972), *Funk Bros. Seed Co. v. Kalo Inoculant* Co., 333 U.S. 127, 130 (1948), *Mackay Radio & Tel. Co. v. Radio Corp. of Am.*, 306 U.S. 86, 94 (1939).

But it is also established by *Diehr* and earlier cases that the mere fact that a patent claim recites a law of nature does not necessarily render the claim unpatentable: "It is now commonplace that an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr*, 450 U.S. at

187; *see also Flook*, 437 U.S. at 590 ("[A] process is not unpatentable simply because it contains a law of nature."). Thus the first to discover a law of nature or natural phenomenon can obtain a patent for a practical application of his discovery. But this does not end the inquiry under Section 101. It must still be determined whether the patent claim is merely seeking patent protection for the law of nature in the abstract. *Diehr*, 450 U.S. at 191.

Diehr identifies two inquiries to determine whether a claim that is directed to a practical application of a law of nature covers the law of nature itself. The first inquiry is whether the claim preempts all practical uses of the law of nature. In *Diehr*, the Court found that the claimed process of curing synthetic rubber, using as part of the process a mathematical equation, did not "pre-empt the use of that equation" but permissibly foreclosed the use of the equation only in conjunction with all of the other steps in the claimed process. *Id.* at 187. *Compare Gottshalk v. Benson*, 409 U.S. 63, 72 (holding that a patent claim that "wholly pre-empts" a mathematical formula used in a general purpose digital computer is directed solely to a mathematical algorithm, and therefore does not define statutory subject matter under Section 101). The Court found the mathematical process claimed in *Benson* "so abstract and sweeping as to cover both known and unknown uses of the BCD [binary coded decimal] to pure binary conversion." 409 U.S. at 68, *citing O'Reilly v. Morse*, 56 U.S. (How.) 62, 113 (1852).

The preemption inquiry under *Diehr* and *Benson* thus necessarily involves an examination of the breadth of the claim. Nonetheless, the Federal Circuit stated recently that

an examination of the scope of the patent claim is not a proper part of a Section 101 analysis:

> [T]he claimed invention is without question a "composition of matter" or an article of "manufacture" within the terms of § 101. Accordingly, the claimed invention represents subject matter eligible for patent protection under § 101. **With that conclusion, the inquiry under § 101 ends... The scope of the claims is not relevant to subject matter eligibility. Subject matter does not take on a different eligibility status with adjustments in the scope of the proposed claim.**

SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1342 (Fed. Cir. 2005) (emphasis added).

While this statement by the Federal Circuit in *SmithKline* might have been intended to apply only to patent claims which do not implicate a law of nature, the statement *per se* is incorrect under *Diehr*. If this restrictive view of the scope of a patentable subject matter inquiry under Section 101 is followed, it could lead to the improper endorsement of a claim covering a law of nature, in contravention of *Diehr*.

Even if it is found that the claim does not preempt the law of nature at issue, *Diehr* still requires an examination of whether the claim contains merely an "insignificant addition" to the law of nature. In *Diehr*, the Court explained that in *Flook*, it had rejected "the argument that because all possible uses of the mathematical formula were not pre-empted, the

claim should be eligible for patent protection." *Diehr*, 450 U.S. at 193 n.14. The Court further explained as follows:

> A mathematical formula as such is not accorded the protection of our patent laws, *Gottschalk* v. *Benson*, 409 U.S. 63 (1972), and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment. *Parker* v. *Flook*, 437 U.S. 584 (1978). **Similarly, insignificant postsolution activity will not transform an unpatentable principle into a patentable process.**

Id. at 191-192 (emphasis added).

The inquiry under Section 101 as to whether the claim comprises merely an "insignificant addition" to the law of nature is not to be confused or conflated with the prior art-based anticipation and obviousness inquiries under Sections 102 and 103. In *Diehr*, the Court made it clear that the issue of whether a patent is directed to patentable subject matter under Section 101 is a threshold issue, separate from the analysis of patentability under other sections of the Patent Act:

> It has been urged that novelty is an appropriate consideration under § 101. Presumably, this argument results from the language in § 101 referring to any "new and useful" process, machine, etc. Section 101 however, is a general statement of the type of subject matter that is eligible for patent protection "subject to the conditions and requirements of this title." Specific conditions for patentability follow and § 102

> covers in detail the conditions relating to novelty. The question therefore of whether a particular invention is novel is "wholly apart from whether the invention falls into a category of statutory subject matter."

Id. at 189-190 (citations omitted).[3]

Recently, the Federal Circuit in *EMI Group North America, Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342 (Fed. Cir. 2001), suggested that a law of nature which is recited in a claim should be treated as if it were prior art. The court in *EMI* stated that the "recitation of a law of nature does not distinguish a claim from prior art." 268 F.3d at 1351, *citing Funk Bros. Seed Co.*, 333 U.S. at 130. This statement is contrary to this Court's holding in *Funk Bros.* as clarified by *Diehr*. While the recitation of a law of nature that is inherently present in the prior art will not distinguish a claim from the prior art, the Federal Circuit's broad statement in *EMI* incorrectly suggests that any law of nature, even one that is not inherent in the prior art, should be treated as if it were prior art under Section 102. In *Diehr*, the Court dispelled this reading of its prior holdings in *Funk Bros.* and *Flook*, pointing out that this interpretation "would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Diehr*, 450 U.S. at 189 n.12. Thus, the Federal Circuit's statement in *EMI*, if applied broadly to all claims reciting

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3. The question posed by the Petitioner also improperly merges the inquiry as to whether a claim meets the requirements of Section 112 with the issue of whether the claim is directed to an unpatentable law of nature or basic scientific principle.

laws of nature, would severely restrict the scope of patentable subject matter, contrary to the standard enunciated in *Diehr*.

When the first to recognize a law of nature obtains a patent directed to a prior art device, composition or process in combination with the newly discovered law of nature, the patent can be found invalid for anticipation under Section 102 only when the law of nature was inherently present in the prior art. The *EMI* court held that "theoretical mechanisms or rules of natural law that are recited in a claim, that themselves are not patentable . . . do not need to be recognized by one of ordinary skill in the art for a finding of inherency" because "a person of ordinary skill does not need to recognize that a method or structure behaves according to a law of nature in order to fully and effectively practice the method or structure."[4] 268 F.3d at 1351. But in a case where the newly discovered law of nature is not inherently present in the prior art, a Section 102 analysis alone will not guard against the improper monopolization of a law of nature. A separate threshold analysis under Section 101 is particularly important in this situation.

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4. *See also Schering Corp. v. Geneva Pharms., Inc.* 339 F.3d 1373 (Fed. Cir. 2003). In *Schering*, the Federal Circuit resolved a long-standing issue in its case law on the doctrine of inherent anticipation: whether recognition of the inherent feature in the prior art is required. The court held that inherent anticipation does not require that the inherent feature be appreciated by those skilled in the art at the time of the prior art patent when the feature is a necessary and inevitable consequence of the earlier invention. *Id.* at 1378.

II. THE CIRCUMSTANCES IN WHICH A SECTION 101 ANALYSIS IS APPROPRIATE SHOULD NOT BE RESTRICTED.

One of the reasons that courts may fail to conduct a threshold Section 101 analysis under *Diehr* is that it is often difficult to identify the situations in which such an analysis is required. The recital of a law of nature or a natural phenomenon as a claim element should alert a court to the need for a threshold Section 101 analysis. In determining whether the claim recites a law of nature, the court should examine how the inventor describes his invention in the written description and file history.

But it is not appropriate to restrict the circumstances in which a Section 101 analysis should be conducted because it is difficult to predict the advances in technology which may raise such concerns in the future. For example, in his concurrence in *SmithKline*, Judge Gajarsa suggested that a Section 101 analysis is necessary in a situation where a man-made composition infiltrates the natural world in such a way that it effectively alters the way that the natural world works and makes infringement essentially unavoidable. He posited the following hypothetical situation:

> Consider, for example, what might happen if the wind blew fertile, genetically modified blue corn protected by a patent, from the field of a single farmer into neighboring cornfields. The harvest from those fields would soon contain at least some patented blue corn mixed in with the traditional public domain yellow corn – thereby infringing the patent. The wind would continue to blow, and the patented crops would spread throughout the

> continent, thereby turning most (if not all) North American corn farmers into unintentional, yet inevitable, infringers. The implication – that the patent owner would be entitled to collect royalties from every farmer whose cornfields contained even a few patented blue stalks – cannot possibly be correct.

SmithKline, 403 F.3d at 1361.

Judge Gajarsa concluded that the most sensible legal reasoning for dealing with this hypothetical situation was a Section 101 analysis and that "patent claims drawn broadly enough to encompass products that spread, appear, and 'reproduce' through natural processes cover subject matter unpatentable under Section 101." *SmithKline*, 403 F.3d at 1361. We do not take any position on whether the facts presented in *SmithKline* raise an issue of patentable subject matter under Section 101, but, rather, cite the hypothetical situation presented by Judge Gajarsa as an example of the range of circumstances in which the need for a Section 101 analysis may be discerned, particularly as new technology impacts the natural world.

Accordingly, while the Court may provide some guidance on the circumstances in which a threshold Section 101 analysis is needed, we believe that it is impossible to predict all of the situations which may raise issues of patentable subject matter under Section 101 in the future.

CONCLUSION

For the above stated reasons, we see no need to modify *Diehr* and believe that a reiteration of the Court's standards for patentable subject matter as enunciated in *Diehr* will serve to place new emphasis on the essential role of a threshold Section 101 analysis with regard to patent claims that implicate laws of nature or natural phenomena.

Respectfully submitted,

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